## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

AND THE DIAGNOSIS OF CYSTIC FIBROSIS

ALTERED NDPK FUNCTIONS

#### PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, D.C. 20231 Box: Patent Application

Sir:

Please amend the above-identified patent application as follows:

# In the Specification:

Please insert the following new paragraph on page 1, line 2 prior to the first paragraph:

"This application is a continuation of PCT/GB00/00736, filed March 2, 2000, which claims priority to U.S. Provisional Patent Application Serial No. 60/122,426, filed March 2, 1999, which are hereby incorporated by reference."

### In the Claims:

Please amend claims 6, 12, 13, 20, 23, 32, 33, 36, 39, 40, 45 and 48, cancel claims 24, 27, 38 and 42 and insert new claims 51-57 as follows:

- 6. (Amended) A method according to claim 1 wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.
- 12. (Amended) A method according to claim 7 wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.
- 13. (Amended) A method according to claim 7 wherein the effectiveness of a treatment for cystic fibrosis is being tested on the patient.
- 20. (Amended) A method according to claim 14 wherein the method is carried out *in vivo*.
- 23. (Amended) A compound identified by the method of claim 14.
- 32. (Amended) A peptide according to claim 31 which comprises SEQ. ID. NO. 1.
- 33. (Amended) A peptide according to claim 28 further comprising a lipid-solubilising moiety.
- 36. (Amended) A peptide according to claim 33 wherein the lipid-solubilising moiety is a fatty acid.
- 39. (Amended) A pharmaceutical formulation comprising a peptide according to claim 28 and a pharmaceutically acceptable carrier.
- 40. (Amended) A method of treating cystic fibrosis or a chronic sputum producing disorder, the method comprising administering to a patient an effective amount of a peptide according to claim 28.

- 45. (Amended) A peptide according to claim 43 wherein the histidine residue is phosphorylated.
- 48. (Amended) An antibody obtainable by the method of claim 46.

Pursuant to 37 CFR §1.121(c)(1)(iii), a marked up version of these claims accompanies this amendment.

- 51. (New) A method according to claim 4 wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.
- 52. (New) A method according to claim 17 wherein the method is carried out *in vivo*.
- 53. (New) A method according to claim 19 wherein the method is carried out *in vivo*.
- 53. (New) A compound identified by the method of claim 17.
- 54. (New) A compound identified by the method of claim 19.
- 55. (New) A compound identified by the method of claim 21.
- 56. (New) A peptide according to claim 44 wherein the histidine residue is phosphorylated.
- 57. (New) An antibody obtainable by the method of claim 47.

#### REMARKS

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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#### APPENDIX

- 6. (Amended) A method according to [any one of Claims] claim 1 [to 5] wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.
- 12. (Amended) A method according to [any one of Claims] claim 7 [to 11] wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.
- 13. (Amended) A method according to [any one of Claims] claim 7 [to 11] wherein the effectiveness of a treatment for cystic fibrosis is being tested on the patient.
- 20. (Amended) A method according to [any one of Claims] claim 14 [to 19] wherein the method is carried out  $in\ vivo$ .
- 23. (Amended) A compound identified by the method of [any one of Claims]  $\underline{\text{claim}}$  14 [to 22].
- 32. (Amended) A peptide according to [any one of Claims 28 to] <u>claim</u> 31 which [has the sequence KENIIFGVSYDEYR] <u>comprises SEQ. ID. NO. 1</u>.
- 33. (Amended) A peptide according to [any one of Claims] claim 28 [to 32] further comprising a lipid-solubilising moiety.
- 36. (Amended) A peptide according to [Claims] <u>claim</u>
  33 [or 34] wherein the lipid-solubilising moiety is a fatty
  acid.
  - 39. (Amended) A pharmaceutical formulation

comprising a peptide according to [any one of Claims]  $\underline{\text{claim}}$  28 [to 37] and a pharmaceutically acceptable carrier.

- 40. (Amended) A method of treating cystic fibrosis or a chronic sputum producing disorder, the method comprising administering to  $\underline{a}$  [the] patient an effective amount of a peptide according to [any one of Claims]  $\underline{claim}$  28 [to 37].
- 45. (Amended) A peptide according to claim 43 [or 44] wherein the [said] histidine residue is phosphorylated.
- $48.\,$  (Amended) An antibody obtainable by the method of claim 46 [or 47].